# Clinical Study of the WoundCare360 SiteSeal Adjunctive Compression Device Following Interventional Endovascular Procedures – NCT03234894

## Statistical Analysis Plan:

## Document Date: November24, 2015

## STATISTICAL PLAN

### Objective

The purpose of this study is to establish the safety of SiteSeal™ Adjunctive Compression Device.

### Study Design

The study design is a single arm with 90 enrolled patients, open-label, single center clinical trial.

### Handling Missing Data

No imputation will be done for missing data.

### Handling Dropouts

The numbers of patients who enter and complete the trial will be tabulated, and details concerning reasons for withdrawals will be listed.

### Statistical Methods

Primary Safety Analyses

For the risk of each of the two primary safety endpoints, namely common femoral nerve puncture and common femoral artery laceration, percent of patients exhibits the risk and its one-sided 95% upper confidence limit will be shown. We expect very low risk for the above two endpoints. In case that we observe no cases for each of the above endpoints, with 90 patients for the device group, we can claim that we are 95% confidence that the risk is less than 3.3%.

Secondary Safety Analyses

For the risk of each of the major complications and minor complications, percent of patients exhibits the risk and its two-sided 95% upper confidence interval will be shown. For the score of patient discomfort, the mean score and its 95% two-sided confidence interval will be reported.

Baseline Patient Characteristic Data

For each of quantitative baseline data such as age, height, BMI, and blood pressures, etc., the mean score and its 95% two-sided confidence interval will be reported.

For each of qualitative baseline data such as procedure type, presence or absence of peripheral vascular disease, and size of the introducer sheath, etc., its frequency distribution will be shown.

Populations for Analysis

All patients in this study are expected to receive the test device, and they will be categorized as intent-to-treat (ITT) patient population. All analyses will be conducted based on this ITT population.

The calculations will be performed using SAS® software for Windows[1], Version 9.4, Copyright (c) 2002-2012 by SAS Institute Inc., Cary, NC, USA.

**References**

1. SAS OnlineDoc Version Nine for the Web, SAS Institute Inc., Cary, NC, USA. http://support.sas.com/documentation/onlinedoc/sas9doc.html